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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/683,003

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Shiguang Yu

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23909

7590

06/23/2009

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/683,003	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> MINA HAGHIGHATIAN	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07/03/08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Haghighatian.

Receipt is acknowledged of the Amendments, Remarks and a Declaration filed on 07/03/08. Claims 2 and 8 have been amended. No claims have been cancelled or newly added. Accordingly claims **2 and 8** remain pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 2, 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for a method of increasing hair growth in a dog or cat subjected to hair removal comprising feeding the dog or cat a properly nutritious diet comprising from about 0.5 to about 4.5 mg of selenium.**

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

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enablement requirement and whether any necessary experimentation is “undue”. See ***In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998)**. The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546, the court recited eight factors

These factors include, but are not limited to:

- 1) *The breadth of the claims,*
- 2) *The nature of the invention,*
- 3) *The state of the prior art,*
- 4) *The level of one of ordinary skill,*
- 5) *The level of predictability in the art,*
- 6) *The amount of direction provided by the inventor,*
- 7) *The existence of working examples*
- 8) *The quantity of experimentation needed to make or use the invention based on the content of the disclosure.*

*The nature of the invention:*

The claims are directed to increasing the rate of hair growth in dog or cat who have had hair removal and which receive a properly nutritious diet with about 0.5 to about 4.5 mg/kg of the diet on a dry matter basis.

*The state of the prior art and the predictability or lack thereof in the art:*

The prior art of record discloses that dietary supplementation of selenium can increase wool production in sheep, that selenium toxicity in dogs, cats and sheep can

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result in hair loss or alopecia and that selenium should be provided in or reduced to levels which do not result in toxicity. The prior art of record also discloses that hypothyroidism can result in poor hair growth or alopecia and that selenium supplementation is effective in treating hypothyroidism. As such, predictability in the art is low with respect to treatment of poor hair growth or alopecia other than in wool production of sheep, selenium toxicity or hypothyroidism resulting from selenium deficiency.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification provides one example in which hair is shaved from different areas on dogs and the rate of hair growth is measured over time in relation to the amount of selenium (provided as selenomethionine) provided in a diet which is nutritionally balanced and complete for an adult dog except for selenium (Specification, paragraphs 0010-0015). The test showed hair growth of cut hair at each amount tested although at certain amounts (0.034, 0.085, 5.045 mg/kg dietary Se) there was decreased hair growth at week 11 and week 22 compared to other amounts (0.123, 0.527, 1.025 mg/kg dietary Se (Paragraph 0015, Table 1). In an article in which the inventors were the named authors, the article indicated that the daily hair growth for beagle dogs is 0.34-0.40 mm (Yu et al., Page 150). This is higher than any of the daily hair growth rate data set forth in Table 1 of the Specification. As such, the only example provided actually provides evidence the claimed range is not effective to increase hair growth in all animals, especially dogs.

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that they claim increasing hair growth in a cat or dog which receives a properly nutritious diet and was subject to hair removal. The evidence submitted and the prior art of record does not provide evidence that selenium would be effective in increasing hair growth in cats or dogs as claimed. The example in the Specification sets forth hair growth rates in beagles in amounts falling within the claimed range of selenium that are below the daily hair growth rate in beagles and the diet used was deficient in selenium and had to be supplemented with selenium. The prior art discloses or suggests providing amounts of dietary selenium in or reducing amounts of dietary selenium to levels which are not toxic as selenium toxicity can cause poor hair growth or alopecia. The prior art discloses that selenium supplementation can treat hypothyroidism and that hypothyroidism can cause poor hair growth or alopecia. However, the prior art does not disclose that dietary selenium at the levels claimed is generally effective in increasing hair growth in cats or dogs subject to direct hair modification, what ever the case, including clipping. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine that administration of selenium in a "properly nutritious diet" would be effective in increasing hair growth in cats or dogs due to direct hair modification.

*Conclusion*

For the forgoing reasons, the specification is not enabling for the scope of the claims.

***Response to Arguments***

Applicant's arguments filed 07/03/08 have been fully considered but they are not persuasive.

Applicant argues against the enablement rejection and states that the claims are limited to methods of feeding dogs or cats diets with specified ranges of selenium and that Applicants have provided adequate guidance for practicing the invention as claimed. Thus the Applicants believe the claims are enabled.

Applicant's arguments are not persuasive and they are not sufficient to overcome the rejection.

In the Remarks (page 5), Applicants refer to the Declaration of Dr. Yu and state that in sections 5-15, Dr. Yu demonstrates that "although a daily hair growth rate in the prior art reference was reported as higher than those listed in Table 1 of the specification, nevertheless, a person of skill in the art would recognize the reasons for the differences and would conclude that the diets fed the dogs in the current study are effective at increasing the rate of hair growth". However, this is not persuasive. The claims recite an increase in the rate of hair growth in a dog or cat comprising feeding the dog or cat a properly nutritious diet comprising from about 0.5 to about 4.5 mg of selenium per kg of the diet on a dry matter basis. The first issue is the diet. According to Dzanis, The association of American feed control officials dog and cat food nutrient profiles: substantiation of nutritional adequacy of complete and balanced pet foods in the united states", a dog's proper food contains about 0.11 mg/kg of selenium and a cat's food contains about 0.1 mg/kg of selenium. Thus the amount of selenium given to

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the cats and dogs according to the instant invention is from 0.1 to 4.5 mg/kg, overlaps the normal daily dose of selenium. The second issue is the evidence of rate of increase. Table 1 shows that both 0.123 and 1.025 mg/kg doses delivered the same results (0.26 mm/day at week 11 and 0.20 mm/day at week 22). There are no data available for other doses between 1.025 and 4.5 mg/kg. The closest dose to the upper limit is 5.045 mg/kg (which is over the therapeutic levels), which produces as much hair growth as 0.034 mg/kg, which is under the therapeutic dose. Thus it is clear that the data provided by the Applicants do not support the claimed method.

On the other hand, the reference provided by the Applicants with the Declaration of 07/03/08, A study of normal hair growth in the dog, by Gunaratnam et al, clearly shows that: a) The rate of hair growth of each individual dog was significantly different, b) there was a significant difference between the means of the growth rates in summer and winter, and c) the rate of hair growth was significantly different in the three regions of the body (see page 449). Furthermore, data in Table 2 shows that, e.g. in the flank area, a mean daily average rate of hair growth of from 0.4 to 0.49 mm was reported. In fact Table 2 shows that all regions, at all times had a comparable or better hair growth rate than those seen in the Table 1 of the instant specification. These hair growth rates are from dogs with normal diets (i.e. normal daily levels of selenium). Therefore, there is no indication that extra selenium has any benefits in or any relation to the rate of hair growth in dogs. This is sufficient evidence that claims are not enabled.



***Declaration***

Declaration of Dr. Yu filed 07/03/08 has been fully considered, but found unpersuasive. Dr. Yu basically compares the data disclosed in the specification with the dissertation of Al-Baghdadi. Dr. Yu states that Al-Baghdadi's tests were incomplete because only 9 dogs were in the study and 10 hair shafts were measured, and only longest hairs were in the sample region. Dr. Yu also states that the techniques used in the instant specification is much more sophisticated than those used in Al-Baghdadi's study. While these may be the case, the arguments are not sufficient to overcome the rejection. The claims are considered not enabled because there is no evidence that selenium at the given dose (or any other dose) has any effect in the rate of hair growth and Applicants have not shown otherwise in the arguments or the Declaration filed on 07/03/08. As stated above, the amount of selenium in the normal daily diet of cats and dogs overlaps the amount claimed. Also the data available in various study suggests that the amount of hair growth shown in the specification is the same or even less than that seen in cats and dogs not treated.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616

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